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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,355	11/03/2003	Jackson Streeter	ACULSR.028A	5229
20995 7590 11/27/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER KIM, TAEYOON	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 11/27/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/700,355	STREETER, JACKSON	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 16-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/2007 has been entered.

Claims 1-10, 14 and 15 have been canceled, claims 20-27 are newly added, and claims 11-13 and 16-27 are pending and have been considered on the merits. All arguments have been fully considered.

Response to Arguments

Applicant's arguments with respect to claims 11-13 and 16-19 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

The information disclosure statement filed 6/22/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because English translation is not available for those foreign patent applications. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with

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the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 and 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “enhancing the in vitro cell culture” does not clearly point out what subject matter the phrase intends to claim. It could be interpreted as proliferation of cells in the culture, differentiation of cells in the culture or increasing protein production, etc.

The phrase “animal cells containing viruses useful for vaccines” does not clearly point out what subject matter the phrase intends to claim. It can be interpreted as animal cells expressing viral proteins, or animal cells infected by viruses. Furthermore, it is not clear whether the animal cells or viruses are useful for vaccines. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 and 16-27 are rejected under 35 U.S.C. 103(a) as being

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unpatentable over Karu et al. (Il Nuovo Cimento, 1984) in view of Joseph et al. (J. Gen. Virol. 1976).

Claims 11-13 and 16-27 are drawn to a method comprising providing an in vitro cell culture comprising bacteria or animal cells, and 2) delivering an effective amount of electromagnetic energy to the cell culture comprising a power density of at least about 0.01 mW/cm^2 and a wavelength of about 780 nm to about 840 nm (claim 11); a limitation to the power density being about 0.01 to about 100 mW/cm^2 (claim 12); a limitation to the power density being about 0.01 to about 15 mW/cm^2 (claim 13); a limitation to the delivering step comprising delivering a series of pulses of light (claim 17); a limitation to the delivering step comprising at least two treatment periods (claim 18); a limitation to the delivering step proceeding for a period of about 30 seconds to about 2 hours (claim 19); a limitation to the cell culture being in a vessel comprising a source of the electromagnetic energy (claim 20); a limitation to the vessel comprising a bioreactor (claim 21); a limitation to the source comprising a laser (claim 22); a limitation to the source being fixed or removable to the vessel (claims 23 and 24); a method for accelerating the production of vaccine by an in vitro cell culture comprising 1) providing a vessel containing an in vitro cell culture comprising cells, 2) delivering an effective amount of electromagnetic energy to the cell culture comprising a power density of at least about 0.01 mW/cm^2 and a wavelength of about 780 nm to about 840 nm, and 3) manipulating the cell culture such that all the cells receive substantially equal energy (claim 25); a limitation to the manipulating the cell culture being stirring the culture (claim 26); a method for accelerating the production of vaccine by an in vitro cell culture

comprising providing a vessel containing an in vitro cell culture comprising cells, positioning a source of electromagnetic energy within the vessel, and delivering electromagnetic energy to the cell culture comprising a power density of at least about 0.01 mW/cm^2 and a wavelength of about 780 nm to about 840 nm (claim 27).

Karu et al. teach in vitro culture of HeLa cells under various wavelengths (300 to 900 nm including 840 nm; Fig. 1) of low-intensity (from 0.1 to 1 W/cm^2 or 0.8 to 1 mW/cm^2) light with pulse periodic irradiation mode (from 2 to 200 seconds; p.311, 1st paragraph) (see Abstract and p.310, 2nd paragraph). The method of Karu et al. stimulates synthesis of DNA and RNA in HeLa cells, and thus growth of the cells, satisfying the limitation of "enhancing the in vitro cell culture".

Although Karu et al. do not teach the HeLa cells comprising viruses, since it is very well known in the art that HeLa cells are useful for viral vaccine production as taught by Joseph et al. (see Abstract only), it would therefore have been obvious to a person of ordinary skill in the art to try the method of Karu et al. for culturing HeLa cells infected with viruses for viral vaccine production as taught by Joseph et al. Because stimulating growth of HeLa cells infected with viruses in in vitro culture would be beneficial to obtain viral vaccines

The Supreme Court recently states in *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of

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identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

With regard to the limitations drawn to the wavelength and power density, Karu et al. disclose various different setting for irradiation to HeLa cells including the ranges of the currently claimed invention. In addition, a person of ordinary skill in the art would recognize that these ranges are considered as result-effective parameters for the method of irradiating cells in culture, because the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed method are result effective variables. As such, the variables would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d

at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Similarly, although the reference particularly teach bacteria culture exposing electromagnetic energy with a wavelength of 780 to 840 nm, since Karu et al. teach that growth of E. coli bacteria is increased under the action of red light (see p.317, last paragraph), it would have been obvious to a person of ordinary skill in the art to optimize the range of wavelength to obtain optimal growth of bacteria of interest.

In the response to the previous office action in regard to the claim rejection based on van Bruegel, which has been withdrawn due to the amendment and the new ground of rejection, applicant argued that the examiner is assuming that there are cells having absorption peaks in the range and that cultures of such cells would be enhanced

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by such irradiation, and argued that the examiner did not provide any basis for such assumptions beyond the teaching of the current application. The examiner respectfully disagrees with this assertion because it is extremely well known in the art that different cell types behave differently to the low level laser irradiation at different wavelength and power intensity. As Karu et al. disclose HeLa cells behave its unique way to various different wavelength of laser irradiation with different intensity and duration, as shown in spectrum of stimulation upon the different wavelength and intensity, and duration (see Figures of Karu et al.), the effect of various combination of wavelength and intensity of laser would be cell type specific.

With regards to the limitations to the method utilizing a vessel, a bioreactor, a position of a laser source (top surface of a container), or the laser source being fixed or removable to the vessel, or manipulating cell culture by stirring, these would be considered to be options rather than limitations to the steps of the method claimed. Therefore, a person of ordinary skill in the art would know these available options in carrying out the method of Karu et al. in view of Joseph et al., and therefore it would have been obvious to try these options to obtain optimal outcome. In addition, M.P.E.P. §2144.04 states "In re Rose , 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if

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such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.)", "In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.", and "In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is "press fitted" and therefore not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.")". Therefore, scaling up (change in size from tissue culture dish or plate to large scale production of cell culture) or making part integral or separable (laser source fixed or separable from the vessel) would be a prima facie obvious.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21 and 24-29 of copending Application No. 11/339,993. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '993 disclose every limitation of the claims of current application. Thus the claims of '993 anticipate the claims of current application, and hence render the claims of the instant application obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-

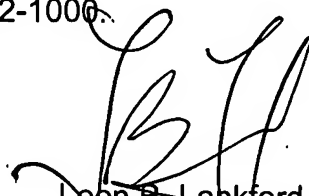
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9041. The examiner can normally be reached on 9:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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